

REMARKS

1. Status of the Claims

Claims 1-38 are pending in this application. Claims 3-4, 7, 16-17, 19-24, 26-27, 31-32, 34-35 and 38 are hereby cancelled without prejudice to pursuing these claims in a continuing application. Claims 1-2, 5-6, 8-15, 18, 25, 28-30, 33 and 36-37 have been amended. Upon entry of these amendments, claims 1-2, 5-6, 8-15, 18, 25, 28-30, 33 and 36-37 are pending and under active consideration. Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present application.

The specification is amended at page 15, lines 20-26 to add a sequence identifier for the recited sequence.

Claim 1 is amended to change from “Use” to “A method.” Claim 1 is also amended to recite “comprising the administration to a person in need thereof a substance,” support for which may be found at original claim 1.

Claim 1 is also amended to recite that the substance may be hGH, a variant thereof with at least 70% sequence identity thereto and which has agonistic activity on the hGH receptor, a variant thereof which is encoded by a DNA sequence which hybridizes to the complement of the native DNA sequence encoding therefor under stringent conditions and which has agonistic activity on the hGH receptor, or a salt derivative thereof, support for which may be found at original claim 4.

Claim 1 is also amended to recite that the substance may also be hGHRH, a variant thereof which has at least 70% sequence identity thereto and which has agonistic activity on the hGHRH receptor, a variant thereof which is encoded by a DNA sequence which hybridizes to the complement of the native DNA sequence encoding therefor under moderately stringent conditions and which has agonistic activity on the hGHRH receptor, or a salt thereof which has agonistic activity on the hGHRH receptor, support for which may be found at original claim 24.

Claim 1 is also amended to recite that the substance may be insulin-like growth factor, support for which may be found at original claim 27. Claim 1 is also amended to recite that the substance may be a nucleic acid encoding the previously mentioned substances, support for which may be found at original claim 32. Claim 1 is also amended to recite that the substance may be a combination of the previously mentioned substances, support for which may be found at original claim 31.

Claim 2 is amended to change from “Use” to “A method.”

Claim 5 is amended to change from “Use” to “A method” and to remove multiple dependencies.

Claim 6 is amended to change from “Use” to “A method” and to remove multiple dependencies.

Claim 8 is amended to change from “Use” to “A method” and to remove multiple dependencies. Claim 8 is also amended to recite a variant that comprise amino acids 177 to 191 of hGH, support for which may be found at original claim 8.

Claim 9 is amended to change from “Use” to “A method” and to remove multiple dependencies. Claim 9 is also amended to recite that the variant is methionyl human growth hormone, support for which may be found at original claim 9.

Claim 10 is amended to change from “Use” to “A method” and to remove multiple dependencies. Claim 10 is also amended to recite that the variant lacks Glu32 to Glu46 of hGH, support for which may be found at original claim 10.

Claim 11 is amended to change from “Use” to “A method.” Claim 11 is also amended to recite that the variant lacks the first eight amino acid residues at the N-terminus, support for which may be found at original claim 11.

Claim 12 is amended to change from “Use” to “A method.” Claim 12 is also amended to recite that the variant lacks the first 13 amino acid residues at the N-terminus, support for which may be found at original claim 12.

Claim 13 is amended to change from “Use” to “A method” and to provide antecedent basis.

Claim 14 is amended to change from “Use” to “A method” and to provide antecedent basis.

Claim 15 is amended to recite that the derivatized substance may be acetylated at the N-terminus, support for which may be found at original claim 15. Claim 15 is also amended to recite that the derivatized substance may be deaminated, support for which may be found at original claim 16. Claim 15 is also amended to recite that the derivatized substance may be sulfoxidized at one or more methionine residues, support for which may be found at original claim 17. Claim 15 is also amended to recite that the derivatized substance may be derivatized at

one or more amino acid side chains with a polyethylene glycol (PEG) moiety, support for which may be found at original claim 26.

Claim 18 is amended to change from “Use” to “A method” and to provide antecedent basis. Claim 18 is also amended to recite that the substance may be administered at a dosage of about 0.1 to 10 mg per person per day or about 0.5 to 6 mg per person per day, support for which may be found at original claim 18. Claim 18 is also amended to recite that the substance may be administered at a dosage of about 1 mg per person per day, support for which may be found at original claim 19. Claim 18 is also amended to recite that the substance may be administered at a dosage administered daily or every other day, support for which may be found at original claim 20. Claim 18 is also amended to recite that the substance may be administered at alternating dosage with the first dosage being higher than the second dosage, support for which may be found at original claim 21. Claim 18 is also amended to recite that the substance may be administered at alternating dosage with the first dosage being about 1 mg per person and the second dosage being about 0.5 mg per person, support for which may be found at original claim 22. Claim 18 is also amended to recite that the substance may be administered at a dosage of about 6 mg per person, about 5 mg per person or about 4.5 mg per person, support for which may be found at original claim 23.

Claim 25 is amended to change from “Use” to “A method” and to remove multiple dependencies. Claim 25 is also amended to recite that the substance is derivatized at one or more side chains of amino acid residues, support for which may be found at original claim 25.

Claim 28 is amended to change from “Use” to “A method” and to correct claim dependency.

Claim 29 is amended to change from “Use” to “A method,” to remove multiple dependencies and to provide antecedent basis.

Claim 30 is amended to change from “Use” to “A method.”

Claim 33 is amended to change from “Use” to “A method,” to remove multiple dependencies and to provide antecedent basis. Claim 33 is also amended to recite that the substance may be administered subcutaneously, support for which may be found at original claim 33. Claim 33 is also amended to recite that the substance may be administered intramuscularly, support for which may be found at original claim 34. Claim 33 is also amended

to recite that the substance may be administered with an auto-injector, support for which may be found at original claim 35.

Claim 36 is amended to recite that the nucleic acid is an expression vector, support for which may be found at original claim 36 and page 24, lines 16-18 of the specification.

Claim 37 is amended to change from “Use” to “A method” and to provide antecedent basis.

2. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the instant application.

Respectfully submitted,

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APPENDIX A

For the convenience of the Examiner, Applicant presents herewith a copy of the claims that will be pending upon entry of the present amendments.

1. (currently amended) A method for the treatment and/or prevention of a Parkinsonism-Plus Syndrome comprising administering to a person in need thereof a substance selected from the group consisting of:

- (a) human growth hormone;
- (b) a variant of (a) which has at least 70% sequence identity thereto and which has agonistic activity on the hGH receptor;
- (c) a variant of (a) having agonistic activity on the hGH receptor and which is encoded by a DNA sequence which hybridizes to the complement of the native DNA sequence encoding (a);
- (d) a salt of (a), (b) or (c);
- (e) human growth hormone releasing hormone (hGHRH);
- (f) a variant of (e) which has at least 70% sequence identity thereto and which has agonistic activity on the hGHRH receptor;
- (g) a variant of (e) having agonistic activity on the hGHRH receptor and which is encoded by a DNA sequence which hybridizes to the complement of the native DNA sequence encoding (e) under moderately stringent conditions;
- (h) a salt of (e), (f) or (g);
- (i) insulin-like growth factor (IGF);
- (j) a nucleic acid encoding any one of (a)-(i); and
- (k) combinations thereof.

2. (currently amended) The method of claim 1, wherein the Parkinsonism-Plus Syndrome is selected from the group consisting of Progressive Supranuclear Palsy (PSP), Multiple System Atrophy (MSA), Parkinson's-amyotrophic lateral sclerosis-dementia of Guam, Generalized Lewy body disease, Corticobasal ganglionic degeneration, Alzheimer's/Parkinson's overlap syndrome, Huntington's disease: rigid variant, Hallervorden-Spatz disease, and Gerstmann-Strausler syndrome.

3. (canceled)
4. (canceled)
5. (currently amended) The method of claim 1, wherein the substance is a naturally-occurring human growth hormone.
6. (currently amended) The method of claim 1, wherein the substance is recombinant human growth hormone.
7. (canceled)
8. (currently amended) The method of claim 1, wherein the variant comprises amino acids 177 to 191 of hGH.
9. (currently amended) The method of claim 1, wherein the variant is methionyl human growth hormone.
10. (currently amended) The method of claim 1, wherein the variant is lacking the 15 amino acid residues from Glu32 to Glu46 of hGH.
11. (currently amended) The method of claim 1, wherein the variant is lacking the first eight amino acid residues at the N-terminus.
12. (currently amended) The method of claim 1, wherein the variant is lacking the first 13 amino acid residues at the N-terminus.
13. (currently amended) The method of claim 1, wherein the substance comprises a dimer of human growth hormone selected from the group consisting of a disulfide dimer connected through interchain disulfide bonds, a covalent irreversible non-disulfide dimer, a non-covalent dimer, and mixtures thereof.
14. (currently amended) The method of claim 1, wherein the substance is chemically derivatized.
15. (currently amended) The method of claim 14, wherein the derivative is selected from the group consisting of:
 - (a) the substance is acetylated at the N-terminus;
 - (b) the substance is deaminated;
 - (c) the substance is sulfoxidized at one or more methionine residues; and
 - (d) the substance is derivatized at one or more amino acid side chains with a polyethylene glycol (PEG) moiety.
16. (canceled)

17. (canceled)

18. (currently amended) The method of claim 1, wherein the substance is administered at a dosage selected from the group consisting of:

- (a) about 0.1 to 10 mg per person per day;
- (b) about 0.5 to 6 mg per person per day;
- (c) about 1 mg per person per day;
- (d) a dosage administered daily;
- (e) a dosage administered every other day;
- (f) alternating daily dosages, wherein the first dosage is higher than the second dosage;
- (g) alternating daily dosages, wherein the first dosage is about 1 mg per person and the second dosage is about 0.5 mg per person;
- (h) about 6 mg per person;
- (i) about 5 mg per person; and
- (j) about 4.5 mg per person.

19. (canceled)

20. (canceled)

21. (canceled)

22. (canceled)

23. (canceled)

24. (canceled)

25. (currently amended) The method of claim 14, wherein the substance is derivatized at one or more side chains of amino acid residues.

26. (canceled)

27. (canceled)

28. (currently amended) The method of claim 1, wherein the IGF is IGF-I or IGF-II.

29. (currently amended) The method of claim 1, wherein the substance is IGF and the patient is further administered IGFBP (Insulin-like Growth Factor Binding Protein) simultaneous, sequential, or separate from the IGF.

30. (currently amended) The method of claim 29, wherein the IGFBP is IGFBP3.

31. (canceled)

32. (canceled)

33. (currently amended) The method of claim 1, wherein the substance is administered in a manner selected from the group consisting of:

- (a) the substance is administered subcutaneously;
- (b) the substance is administered intramuscularly; and
- (c) the substance is administered with an auto-injector.

34. (canceled)

35. (canceled)

36. (currently amended) The method of claim 1 wherein the nucleic acid is an expression vector.

37. (currently amended) A method for the treatment and/or prevention of a Parkinsonism-Plus Syndrome comprising administering to a person in need thereof a cell, wherein the cell produces a substance capable of treating or preventing a Parkinsonism-Plus Syndrome according to the method of claim 1.

38. (canceled)